Basic information

2003/2255(DEC) DEC - Discharge procedure	Procedure completed
2002 discharge: European Agency for the Evaluation of Medicinal Products **Subject** 8.70.03.07 Previous discharges	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	MULDER Jan (ELDR)	10/09/2002

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health, Consumer Policy	GOODWILL Robert (PPE-DE)	01/12/2003

Key events

Date	Event	Reference	Summary
15/10/2003	Non-legislative basic document published	N5-0029/2003	Summary
18/12/2003	Committee referral announced in Parliament		
18/03/2004	Vote in committee		
18/03/2004	Committee report tabled for plenary	A5-0212/2004	
20/04/2004	Debate in Parliament		
21/04/2004	Decision by Parliament	T5-0323/2004	Summary
21/04/2004	End of procedure in Parliament		
21/04/2004	Final act published in Official Journal		

Technical information

Procedure reference	2003/2255(DEC)
Procedure type	DEC - Discharge procedure
Legal basis	Rules of Procedure EP 102
Stage reached in procedure	Procedure completed

Documentation gateway				
European Parliament				
Document type	**Committee**	**Reference**	**Date**	**Summary**
Committee report tabled for plenary, single reading		A5-0212/2004	18/03/2004	
Text adopted by Parliament, single reading		T5-0323/2004 OJ C 104 30.04.2004, p. 0421-0571 E	21/04/2004	Summary
Council of the EU				
Document type		**Reference**	**Date**	**Summary**
Supplementary non-legislative basic document		06196/2004	09/03/2004	Summary
Other institutions and bodies				
Institution/body	**Document type**	**Reference**	**Date**	**Summary**
CofA	Non-legislative basic document	N5-0029/2003 OJ C 319 30.12.2003, p. 0022-0028	15/10/2003	Summary

Additional information		
Source	**Document**	**Date**
European Commission	EUR-Lex	

Final act	
Budget 2004/0710 OJ L 330 04.11.2004, p. 0020-0020	Summary

2002 discharge: European Agency for the Evaluation of Medicinal Products

2003/2255(DEC) - 09/03/2004 - Supplementary non-legislative basic document

PURPOSE : to present a Council Recommendation on the discharge to be given to the Director of the European Agency for the Evaluation of Medicinal Products in respect of the implementation of the budget of the European Agency for the European Agency for the evaluation of medicinal products for the financial year 2002. CONTENT : taking into account the positive Report from the Court of Auditors on the financial statements of the Agency, the Court recommends that the European Parliament give discharge to the Director of the Agency in respect of the implementation of the budget for the financial year 2002. To recall, EUR 12,2 million (90 %) of the EUR 13,5 million in appropriations carried forward from the financial year 2001 to the financial year 2002 have been used. EUR 6,8 million in appropriations have been carried forward from the financial year 2002 to the financial year 2003 and EUR 4,2 million have been cancelled. This recommendation includes comments made by the Council on the discharge to be given to the Agency. The Council welcomes the fact that the Court of Auditors has been able to obtain reasonable assurance that the Agency's annual accounts for the financial year ended 31 December 2002 are reliable and that the underlying transactions, taken as a whole, are legal and regular. However, some observations need to be made. The Council notes with satisfaction the efforts being made by the Agency to put in place a revised procedure to bring

the processing of inspection fees in line with the principle of annuality. About the global sum advances received by the Agency, the Council stresses the importance of finding a procedure in order to make the link between the customer deposits and their uses clearer. Finally, the Council asks that the implementation of internal control procedures necessary in order to carry out efficient verification of invoices be improved as quickly as possible.

2002 discharge: European Agency for the Evaluation of Medicinal Products

2003/2255(DEC) - 21/04/2004 - Text adopted by Parliament, single reading

The European Parliament adopted the report by Jan MULDER (ELDR, NL) concerning the granting of discharge to the Director of the European Agency for the Evaluation of Medicinal Products, in respect of the implementation of its budget for the financial year 2002. The Parliament records its comments in the accompanying resolution. Firstly, on the issue of the implementation of the budget (financial rules), the Parliament welcomes the agreement that was reached between the Agency and the Commission on the payment of the Community subsidy in three instalments, intended to help reduce carry-overs. Moreover, it notes the revised procedure put in place, in agreement with the Court of Auditors, for the processing of commitments in the event that an inspection is decided upon, with a view to better complying with the annuality principle and invites the Agency to further comment on whether the use of differentiated appropriations might have a positive effect on the level of carry-overs. Parliament stresses however that, despite the agreement reached, the carry-overs situation resulting from the procedure applied for inspections by a national agency would need to be improved. As regards the financial statements, Parliament notes the Agency's reply concerning the steps taken to improve the processing of advances paid for inspections and fees actually due; expects the Agency to further clarify the information given on the use of customers deposits. Lastly, as regards the internal control procedures, Parliament welcomes the Agency's decision to formalise the functioning of an internal audit service; expects the Agency and the Commission to take further steps towards improving cooperation between that service and the Commission's Internal Audit Service (IAS). In parallel, the Parliament has made a series of horizontal points on all of the Agencies' discharges which can be summarised as follows: - Internal audit and control measures : Parliament reiterates the position taken in its resolutions 2003 accompanying the discharge given to the Agencies for 2001 as regards the implementation of the new Financial Regulation and invites the Commission and the Agencies to continue their cooperation, in particular in the areas of accounting, internal audit, management and control procedures, so as to ensure that a coherent harmonised framework for the functioning of the Agencies is established. It recalls that it expressed concern in the discharge resolution for 2001 concerning the lack of controls on the agencies carried out by the internal audit service of the Commission (IAS). Parliament expresses grave concern that such controls do not seem to have been carried out this year. It stresses that it is essential that the Agencies be required to submit to the investigative powers of OLAF under the same conditions as the other institutions. - Financial Management : Parliament invites the Agencies to better explain their analysis and to indicate in particular which of their activities of a multi-annual nature might be financed by such appropriations. The Commission is invited to present its position on such a solution and, should it consider that this solution is not feasible, to outline alternatives allowing for a substantial reduction in carry-overs. - Review of the agencies : the Parliament states that that, prior to any decision to set up an agency, the Commission must make arigorous analysis of the need for and added value of the functions that the agency will perform, with an eye to the principles of subsidiarity, budgetary rigour and procedural simplification. Like last year, the Commission is called upon to make a general study of activities currently carried out by various Community bodies that might overlap or serve the same goals, and to propose appropriate solutions, including the possible mergers of agencies. Parliament is concerned by the fact that there is an imbalance between administrative and operational expenditure in many Agencies, with administrative expenditure exceeding expenditure for operational purposes. The Commission and the Agencies are called upon to set targets and a timetable to reduce the level of administrative expenditure as a proportion of total expenditure. The Agencies are encouraged to : - improve cooperation between themselves in order to meet their needs in specific areas (for example, software development) and reduce costs, rather than adopt solutions which were initially designed for the purposes of the Commission but which often prove to be too cumbersome and complicated for the Agencies' specific needs; - organise and develop a close working relationship with the competent parliamentary committees; invites its standing committees with competence in the areas of activity of each of the Agencies to co-ordinate their action with the Committees of Budgets and Budgetary Control, with a view to ensuring efficient monitoring of the activity of the Agencies. - New sources of financing : Parliament calls on the Commission and the Agencies to come forward with constructive proposals with regard to further development of new sources of additional financing, which would increase the level of self-financing. It welcomes the financial contributions of some Member States and regions to the agencies located on their area and considers it important for Council and the Commission to demand such contributions, especially when new agencies are set up. - Harmonised operating framework : Parliament recalls its that the multitude of different forms in the existing agencies' structures was thought to be "neither transparent nor comprehensible. Therefore, it has invited the Commission to present appropriate proposals, aimed at creating such a harmonised framework for the agencies, prior to or at least in parallel with the presentation of the legislative proposals for the new agencies; insists that an interinstitutional agreement spelling out common guidelines is a pre-condition for creating the harmonised framework. - Staff policy : the Parliament considers that the staff policy of the Agencies should comply with the Financial Regulation, the Staff Regulations and the best practice generally followed by the Institutions. The Parliament recalls the principle that the Agencies should as far as possible employ staff on temporary contracts, in order to maintain flexibility and efficiency. In this respect, it is concerned about the serious anomalies detected in connection with the selection procedures of the European Monitoring Centre for Drugs and Drug Addiction and that selection procedures organised by the Agencies should meet the same standards as those organised by the European Personnel Selection Office (EPSO) and that they should not be perceived as a backdoor for easy entry into the European civil service. Lastly, the Commission is invited to make proposals in order toensure that the Agencies benefit from appropriate support from the EPSO when organising selection procedures and that there is a mechanism in place to validate the outcome of such procedures externally before recruitment takes place.

2002 discharge: European Agency for the Evaluation of Medicinal Products

2003/2255(DEC) - 21/04/2004 - Final act

PURPOSE : to grant discharge to the European Agency for the Evaluation of Medicinal Products, in respect of the implementation of its budget for the financial year 2002.

LEGISLATIVE ACT : Decision 2004/710/EC of the European Parliament concerning discharge to the Director of the European Agency for the Evaluation of Medicinal Products for the financial year 2002.

CONTENT : with this present Decision, the European Parliament gives discharge to the Director of the European Agency for the Evaluation of Medicinal Products, in respect of the implementation of its budget for the financial year 2002.

This Decision is in conformity with the European Parliament’s resolution approved on 21 April 2004 and which is accompanied by a series of which complete the discharge decision (please refer to the summary of the opinion).

2002 discharge: European Agency for the Evaluation of Medicinal Products

2003/2255(DEC) - 15/10/2003 - Non-legislative basic document

PURPOSE : to present the report from the Court of Auditors on the financial statements of the European Agency for the Evaluation of Medicinal Products (EMEA) concerning the financial year 2002. CONTENT : this report concerns the results of the audit performed by the Court of the financial statements of the European Agency for the Evaluation of Medicinal Products for the financial year ended 31/12/2002. This examination has enabled the Court to obtain reasonable assurance that the annual accounts are reliable and that the underlying transactions, taken as a whole, are legal and regular. The report highlights that the final appropriations entered for the financial year amount to EUR 61,3 million, committed to the amount EUR 58,4 million with EUR 51,6 million being paid. The total amount carried over was EUR 6,8 million and EUR 2,9 million was cancelled. The amount of outstanding commitments from the previous year amount to EUR 13,5 million of which EUR 12,2 have been paid and EUR 1,3 million has been cancelled. The report states in particular that Agency dedicates a significant part of its budget to the financing of pharmaceutical supervision systems. As soon as the scientific committees decide to carry out an inspection of a medicinal product, a proposal for a commitment is issued in respect of the fee to be paid to the national agency responsible for carrying out the inspection. This procedure does not allow the principle of annuality to be respected, since delays in carrying out the work mean that the expenditure will be settled during a later financial year. In addition, it increases administrative expenditure as a result of cancellations and new commitments. On the issue of financial statements, the report shows that applying principles of accruals accounting, contrary to the current regulations which provide for cash-based accounting, the Agency included in its revenue EUR 5,2 million due in respect of the financial year 2002 (in 2001, EUR 10,7 million had been included in the revenue). The Agency frequently receives lump-sum advances for examinations which the users of its services are considering requesting. It is difficult to reconcile the amounts customers have paid and the fees actually due. The delays affecting the processing of files partly explain the 75 % increase in the amount of advances not allocated at the end of 2002. Concerning the issue of invoices, these are paid after the authorising officer, who certifies that the service has been performed or the goods delivered, has given his approval. This is issued without any systematic provision of supporting documents. The absence of such information, which is necessary in order to carry out efficient internal control, creates uncertainty and must be remedied. The Agency replies to the criticisms made by the Court. It states in particular that at the beginning of 2003, it put in place a revised procedure to bring the processing of inspection fees in line with the principle of annuality. Improvements have been made to the financial accounts in the perspective of the implementation of the new Financial Regulation. Lastly, there shall be improved internal control procedures for verification of invoices, including checklists and intensified training of staff on financial procedures and controls.